IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO ALL CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' OPPOSITION TO

JOHNSON & JOHNSON'S AND ETHICON'S MEMORANDUM IN SUPPORT OF MOTION TO REVISE CASE MANAGEMENT PROCEDURES RELATED TO STATUTE OF LIMITATIONS AND ESTOPPEL DEFENSES AND MOTION FOR ENTRY OF CASE MANAGEMENT ORDER

Defendant Ethicon's Motion to Revise the current case management orders in place for this litigation recognizes a reality in this litigation: the only way to resolve legal and factual issues across the litigation is to assign cases for work-up and trial. That is a position that the Plaintiffs have long espoused. However, the proposal advanced by Ethicon does not resolve any factual or legal issues; does not advance the process of resolving the litigation on behalf of injured women; and does not assist the Court or the litigants in determining scope of unresolved issues. Perhaps the irony in defendants' motion best exemplifies the problem with their cookie-cutter approach. Defendants actually claim that many of the plaintiffs have not been injured, while simultaneously claiming that the prescriptive period for their claims, which nearly always requires, at a minimum, discovery of injury, has run. In short, as set forth in more detail below, the proposal simply does not work.

Recognizing, however, the need for a definitive plan for working through these cases, the Plaintiffs move that this Court instead enter the Proposed Case Management Order attached hereto as Exhibit 1. As described in more detail below, that Case Management Order provides the Court and the litigants a vehicle to resolve liability, legal and causation issues across a broad range of products.

I. THE PLAINTIFFS' PROPOSED CASE MANAGEMENT ORDER

Exhibit 1 hereto sets for the Plaintiffs' Proposed Case Management Order for this Court. This Order, which is largely based on the prior Case Management Orders that this Court has entered in the Boston Scientific and Bard MDLs, provides a vehicle to allow this Court and the litigants to address legal, factual and liability issues in an orderly fashion. Significantly, it provides for serial, consolidated trials against Ethicon commencing in late 2015, the same time frame proposed by Ethicon in their motion. Specifically, the Case Management Order contemplates five trial groupings, organized by product and state: TVT-S (GA); Prolift (FL); TVT-O Mechanical Cut (IL); Prolift +M (WV); and TVT Mechanical Cut (AZ).

The Plaintiffs' Proposed Order differs from the Defendant's in several important ways. First, it recognizes that the actual inventory of cases before the Court consists of more than just the TVT and TVT-O cases discussed by Ethicon. Therefore, it allows for work up of 5 separate products – including the TVT and the TVT-O. Second, it recognizes that the cases before the Court include pelvic organ prolapse cases, as well as stress urinary incontinence cases. Therefore, it allows for the work up of two trial groupings for the Prolift and Prolift +M, POP products manufactured by Ethicon. It also allows for work up of three trial groupings for SUI products – TVT, TVT-O and TVT-S. Third, it recognizes the fact that this Court has already addressed and considered the application of particular state laws to the facts of these cases.

Therefore, it proposes case grouping from states where this Court has provided prior guidance to litigants on legal issues, allowing the litigants and the Court to build on the progress that has already been made. Finally, the proposal recognizes that the burden of working hundreds of cases up at the same time can outweigh the benefits, particularly where there is no trial plan proposed. Therefore, it proposes the work up of a total of eight (80) cases with a staggered schedule – enough cases to allow the parties and the Court access to sufficient information to value and evaluate cases.

Perhaps the most significant part of the Plaintiffs' Proposed Case Management Order is that it allows Ethicon to resolve the issues that it addressed in its own motion. Defendants' proposal to address individual issues en masse is misguided – each of the issues raised requires an analysis of facts and law, not simply a review of certain medical records. Thus, to achieve their stated goal of addressing causation and SOL issues, a plan that allows all parties to carefully and mindfully address cases without making speculative guesses as to what the evidence may show across a population of unspecified cases. For example, a statute of limitations defense is state law-specific, discovery rule-dictated and fact-intensive. It cannot be evaluated in a vacuum for swaths of plaintiffs, but instead must be addressed with a careful review of facts and law applicable to particular cases. Furthermore, defendants are obliged to prove their affirmative defenses – and the Plaintiffs' Proposed Case Management Order allows them the opportunity to do just that in 80 specific cases without requiring the Plaintiffs to show cause why their cases should not be dismissed on limitations grounds (thus turning the concept of burden of proof on its ear).

Similarly, to the extent that Ethicon has concerns about causation issues – including injuries – those must be resolved on a case by case basis. The injuries that these women suffer

cannot be summarily dismissed as Ethicon suggests – and to propose that women who are injured by these products should be denied the opportunity to fully and completely address those injuries (including injuries that do not implicate subsequent surgical procedures) is an affront to the legal system, as well as the women who have brought these claims. The Plaintiffs' Proposed Case Management Order allows for Ethicon to receive the information that they want – including medical records, depositions, and the like – while simultaneously recognizing the Plaintiff's right to produce all evidence that supports her claims in the case for the Court's consideration, including physician testimony and expert testimony.

In summary, the Plaintiffs' Proposal allows all litigants the ability to fully discover evidence that supports their claims (including Defendants' affirmative defenses) and to reach a resolution of those claims based on actual facts, as opposed to the wild speculation that underscores Ethicon's entire briefing on these matters. It also allows for the appropriate use of the civil litigation system to achieve an orderly resolution of key issues in these cases. Accordingly, the Plaintiffs respectfully request that this Court enter the Proposed Case Management Order attached hereto at Exhibit 1.

II. ETHICON'S MOTION IS UNWORKABLE BECAUSE IT UNILATERALLY IMPOSES BURDENS NOT CONTEMPLATED BY THE RULES OF CIVIL PROCEDURE ON PLAINTIFFS WHILE SIMULTANEOUSLY DELAYING PROPER DISCOVERY AND WORK UP OF TRIAL CASES

Unlike the Plaintiffs' Proposal, Ethicon has submitted a plan that imposes unilateral burdens on the Plaintiffs and does nothing to resolve this litigation across all products and all conditions. Plaintiffs do not believe that this Court need even address many of the unsubstantiated arguments and "facts" asserted by Ethicon; however, many of the arguments raised in favor of their proposal are without merit and they must be addressed herein.

1. **Plaintiffs' obligation is to produce medical records documenting their implantation and any other records they possess.**

As Plaintiffs indicated in their response to Defendants' original motion to revise, Plaintiffs do not contest their obligation to provide proof of implantation with one of Defendants' products. Plaintiffs recognize this Court has found that Plaintiffs' duty to investigate includes securing records confirming implantation. But Defendants want much more. Defendants demand records that contain the particular product code for the device implanted. (Memorandum ("Memo") at ¶ 2). According to Defendants, if the surgical report does not contain the specific product code, Plaintiffs must order or subpoena all their records until they find a record with the identification code (and all this to be done within 30 days).[1]

Defendants offer no legal basis for their demand, and that is because there is none. While Plaintiffs must perform a sufficient pre-suit investigation to confirm that Plaintiff was implanted with Defendants' product and that the Plaintiff has a cognizable claim, there is simply no obligation or basis for imposing this additional burden on Plaintiffs unilaterally. A surgical report that identifies the brand name of the product is more than ample proof for a good faith lawsuit. Furthermore, Defendants offer no reason to believe that medical records have incorrectly identified their products to such a degree that Plaintiff's counsel could reasonably rely solely on records containing identification numbers.

Moreover, pursuant to PTO 17 and the authorizations attendant to the Plaintiff Profile Form, Defendants have had the ability to order complete medical records for each and every Plaintiff in this litigation. Presumably, since Defendants have had these authorizations for many

[1] Defendants are not entitled to the relief they seek. But even if they were, they certainly would not be entitled to a 30-day turnaround. As Defendants are well aware, and have frequently argued to this Court, securing medical records often takes longer than a single month. (Memo at ¶ 2)

months and even years in some cases, they already have access to much of the information they seek, including the product codes if they believe them to be truly important. This new burden would certainly divert Plaintiffs from pursuing trial-set cases, and it might deter or delay the filing of legitimate cases by making the process costly and burdensome. Neither result is a legitimate goal of the discovery process.

Finally, in order to address the precise issue that Defendant again raises in its latest salvo (conveniently timed just a few days prior to this Court's next status conference) the parties have already retained independent statisticians and accountants to conduct a random sampling on 800 hundred cases. This process has provided Ethicon more than sufficient information to evaluate the docket of cases in this MDL, and has thus far further revealed that every plaintiff but three had been implanted with defendants' products. The other three were implanted with a different mesh device and had apparently inadvertently sued the wrong manufacturer.

2. Ethicon's Definition of Plaintiff "Injury" Is Misleading and Denies Injured Women Access to the Legal System

Defendants also request that Plaintiffs be required to order or subpoena myriad medical records. The reason they give is that a significant number of Plaintiffs have not had revision surgery. (Memo at ¶ 3) Defendants thus infer that "[a] substantial number of MDL participants may have no documented complaint of injury before a decision to file suit." (Memo at ¶ 3)

Defendants' conclusion does not follow from the facts. Frankly, a substantial majority of people who have serious complications from any type of surgery elect not to have yet another surgery which may exacerbate their injuries or create new ones. Many people fear undertaking the same treatment that caused their problems in the first instance. Many women suffer complications related to Ethicon's products that cannot be treated through subsequent surgeries. Doctors are often not sanguine about the benefits of surgical removal either. Two widely

disseminated studies cast doubt on whether surgery actually overcomes mesh side-effects in patients. (Amy Norton, *Removal of Faulty Mesh for Incontinence: Experts say there's still no clear-cut answer as to whether or not to have surgery*, INCONTINENCE & OVERACTIVE BLADDER HEALTH CENTER (May 19, 2014)).[2]

What we do know is that chronic wound healing and excessive scarring from implantation will eventually lead to mesh shrinkage. (L. Velemir, et al, *Mesh shrinkage: How to assess, how to prevent, how to manage?*, Presentation, INT'L UROGENECOLOGICAL ASSOC. (June 16-20, 2009, attached hereto as Exhibit 3). And we know from Defendants' own medical director's admission that 59 percent of women implanted with their products experience shrinkage of the mesh. (Depo. of Dr. Piet Hinoul, September 18, 2012, Ex. 4 at 960:13-967:2) Yet, nowhere near 59 percent of those with mesh have filed suit. Many women experience chronic pain from Defendants' products but do not choose to have yet another surgical procedure to try to right the wrongs of the first.

Plaintiffs' counsel acts in good faith when counsel listens to and believes their clients' description of their suffering without demanding secondary verification. A Plaintiff is injured if she experiences severe pain, even if medical records cannot confirm the existence of an injury. Indeed, there are entire medical fields that focus on "soft tissue" injuries that cannot be confirmed by tests or examinations. Moreover, in some jurisdictions, women may recover damages for emotional distress caused by a Defendant's misdeeds, even without a present physical injury. *See, e.g., Faya v. Almaraz*, 620 A.2d 327, 336-37 (Md. App. 1993) (upholding damage claim for fear of contracting AIDS from HIV-surgeon despite no evidence Plaintiffs were HIV-positive); *Wetherill v. Univ. of Chicago*, 565 F. Supp. 1553, 1559-60 (N.D. Ill. 1983)

[2] www.webmd.com/urinary-incontinence-oab/news/20140519/removal-of-faulty-mesh-for-incontinence-may-not-improve-womens-symptoms, attached hereto as Exhibit 2.

(upholding claim for emotional distress due to fear of developing cancer from ingesting DES despite no evidence of physical injury). Thus, Plaintiff counsel does not violate any ethical obligations in filing complaints without ordering medical records supporting injury claims.

Furthermore, Defendants' demand that Plaitniffs secure precise records not in their possession exceeds the scope of discovery prescribed by the Federal Rules, as well as this Court's pretrial orders. The Federal Rules require litigants to produce only those documents in their possession, custody and control. *See* FED. R. CIV. P. 34(a); *Patrick v. Teays Valley Trustees, LLC*, 297 F.R.D. 248, 262 (N.D. W. Va. 2013), *aff'd*, 298 F.R.D. 333 (N.D.W. Va. 2014). So does this Court's Pretrial Order No. 17.

A litigant does not "control" her medical records. In *Clark v. Vega Wholesale Inc.*, 181 F.R.D. 470 (D. Nev. 1998), the court noted that the essence of "control," for discovery purposes, is a party's legal right of access to materials. The court held that a Plaintiff has no legal right to medical records held by a third party, despite the fact that the Plaintiff could obtain the records with a valid authorization. Indeed, "medical care providers maintain custody or control of medical records." *Id.* at 472 (citation omitted). In a subsequent decision, the same court referred to a line of cases holding that "a patient does not have control of medical records that are in the possession, custody or control of his medical providers." *Powell v. Texvana, Inc.*, No. 2:09-cv-01079-LDG-GWF, 2010 WL 4791507, at *1 (D. Nev. Nov. 18, 2010). Moreover, "the party seeking the records can obtain them by serving a subpoena on the medical provider." *Id.*[3]

Numerous other courts concur. *See, e.g., Neal v. Boulder*, 142 F.R.D. 325, 327 (D. Colo. 1992) ("Plaintiffs do not have custody of the medical records being sought."); *Zavala-Basquez v.*

[3] Defendants have made no claim that any Plaintiffs have failed to provide a sufficient signed authorization form to facilitate Defendants' obtaining of records, and even if they had, PTO 17 provides the mechanism by which they can obtain relief.

Allstate Indem. Co., No. C8-5673BHS, 2009 WL 3063078, at *2 (W.D. Wash. Sept. 21, 2009) ("Plaintiffs' DSHS records are not within their control and Defendant has other means of obtaining the information."); *Greene v. Sears, Roebuck & Co.*, 40 F.R.D. 14, 16 (N.D. Ohio 1966) ("It must be borne in mind that Rule 34 extends only to documents which an adverse party has 'in his possession custody or control.' From the record, it does not appear, and it seems quite unlikely, that any of the [treating physician notes] are now in the possession or custody of the plaintiff or her counsel."); *Dobbey v. Randle*, No. 10 C 3965, 2014 WL 1364428, at *2 (N.D. Ill. Apr. 7, 2014) ("Plaintiff's [unproduced] medical records are in [the Illinois Department of Corrections'] possession, custody, and control."); *U.S. v. Sarras*, 575 F.3d 1191, 1215 (11th Cir. 2009) (a Plaintiff's medical records are in the control of the facility holding them).

The fact that Plaintiffs have the ability to obtain their medical records via authorization does not change this fundamental fact. After all, Plaintiffs' consent does not obligate the provider to produce the records on demand. It simply authorizes the provider to produce them under HIPAA. The provider may still demand a subpoena (i.e., a court order) from either party prior to production. Federal courts have thus held that the ability of a Plaintiff to obtain his records with an authorization form does not constitute control for purposes of discovery. As Judge James Seibert of this Circuit wrote:

> This Court agrees with those courts finding that Rule 34 requires an item in a request for production be in the possession, custody, or control of the served party and that medical records held by a physician do not meet this description. The plain language of the Rule provides that a request for production must involve items "which are in the possession, custody or control of the party upon whom the request is served." Fed. R. Civ. P. 34(a). There is no provision in Rule 34 for requesting documents from a party that are possessed by another person. While a patient may be able to request medical records from a physician, the records are not sufficiently within the patient's control to qualify under Rule 34.

Ayers v. Continental Casualty Co., Civ. Act. No. 5:05-CV-95, 2007 WL 1960613, at *7 (N.D.W. Va. July 2, 2007).[4]

Magistrate Judge Eifert has recognized in this litigation that health care providers control medical records, not the patient. In distinguishing between a patient's control of tissue explants and the provider's control of medical records, Judge Eifert stated:

> [M]y understanding of medical records is that those records belong to the medical provider. The medical provider creates the records. It's the thought process of the medical provider. And from the beginning of time, those records have belonged to the medical provider.

(Transcript, Hearing, June 13, 2014, Ex. 5 at 4:17-21.)[5]

The Rules do not authorize the relief Defendants seek. Defendants can obtain any records they require through the signed medical authorization forms they have received from each Plaintiff. But Defendants are not entitled to an order requiring Plaintiffs to order and subpoena the records themselves – at least, not before a case has a trial setting.

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[4] *See also Pham v. Wal-Mart Stores, Inc.*, No. 2:11-cv-01148-KJD-GWF, 2012 WL 3730565, at *2 (D. Nev. Aug. 28, 2012) ("The Court finds that Plaintiff does not have possession, custody or control of the medical records, and therefore Plaintiff is not obligated to produce such records under Rule 34. Defendants can secure copies of the relevant documents from the appropriate medical provider or state or local agency as readily as Plaintiff."); *Candelaria v. Erickson*, No. 01 Civ. 8594 LTS RLE, 2006 WL 1636817, at *2 (S.D.N.Y. June 8, 2006) ("Since the records at issue are not under [the plaintiff's] possession, custody or control, by executing the updated releases, he would be authorizing only the disclosure of his medical records."); *Clark*, 181 F.R.D. at 672 ("The relationship between the Plaintiff and her doctor is not sufficient to establish control. In fact, the Defendants can secure copies of the requested documents from the custodian of the records as readily as the Plaintiff.").

[5] The arguments in this section of the brief appeared almost *verbatim* in Plaintiffs' response to Defendants' motion to revise management procedures (Document No. 1428), yet defendants declined to address these issues in either the memorandum at issue or their reply brief.

3. Defendants' unrealistic desire to pursue its limitations defense against countless cases in one fell swoop does not justify deviating from the Rules.

Defendants contend that the Court should go beyond the rules and order Plaintiffs to order or subpoena all their medical records for Defendants so Defendants can move for summary judgment against numerous Plaintiffs on the statute of limitations *en masse*. Defendants cite no authority for the proposition that the assertion of an affirmative defense somehow broadens Plaintiffs' discovery obligations. But Defendants' claim that limitations can be decided for all Plaintiffs based solely on a review of medical records is erroneous. The limitations analysis varies too much by state law and case facts.

It is beyond the scope of this filing to discuss how statutes of limitations are treated in every jurisdiction.[6] However, the general rule is that defenses based on prescriptive periods are affirmative defenses. *See, e.g., Forshey v. Jackson*, 671 S.E.2d 748, 751 n. 8 (W. Va. 2008) ("Statutes of limitations and repose are affirmative defenses.") The party asserting such a defense has the burden of proving it. *See, e.g., Williams v. Precision Coil, Inc.*, 459 S.E.2d 329, 339 n. 17 (W. Va. 1995). Most states have adopted a discovery rule that provides that the prescriptive period does not begin until the Plaintiff knew or should have known of her cause of action (at least of her injury). *See, e.g.,* Tyler T. Ochoa & Andrew J. Wistrich, *Limitation of Legal Malpractice Actions: Defining Actual Injury and the Problem of Simultaneous Litigation*, 24 SW. U. L. REV. 1, 26-27 (1994) ("most states have adopted the discovery rule").

Under many states' laws, a cause of action does not accrue until a Plaintiff knew or should have known of both the injury and its cause. *See, e.g., Goodwin v. Bayer Corp.*, 624 S.W.2d 562, 567 (W. Va. 2005) (West Virginia law); *Morgan v. Petroleum Prods. Equipment*

[6] Simply for ease of reference, Plaintiffs will cite the law of West Virginia for general principles and the law of at least one other state for more specific principles.

Co., 92 A.3d 832, 829 (Pa. Super. 2014) (Pennsylvania law); *Frideres v. Schiltz*, 540 N.W.2d 261, 269 (Iowa 1995) (Iowa law); *Arthur D. Little Intern., Inc. v. Doovang Corp.*, 928 F.Sup. 1189 (D.Mass.1996) (Massachusetts law). And still in other states, the claim does not accrue until the Plaintiff is aware of the Defendants' wrongful conduct, in addition to injury and cause. *See, e.g., Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 803 (2005) (California law).

It is axiomatic that the limitations inquiry will be different from case to case, depending on both the applicable law and the facts. In no states will limitations begin merely upon implantation of the device. There must be an injury for a cause of action to even exist. And in some cases, the injury will not have occurred until years after the device was implanted. (Velemir, *supra*, at 7) Knowledge of an injury will not start the prescriptive period in many states without proof that the Plaintiff was aware that the mesh had caused her injuries. Even the explant surgery will not begin the limitations period in many states absent proof that the Plaintiff knew that the mesh caused the injuries rather than merely that removal of the mesh would somehow alleviate the injuries. And in states where knowledge of wrongful conduct is required, even a Plaintiff's knowledge that the mesh caused her injury and would have to be removed may be insufficient. In fact, this Court has found that even four revision surgeries did not establish, as a matter of law, that a Plaintiff's causes of action had accrued. *See Sanchez v. Boston Scientific Corp.*, Civ. Act. No. 2:12-cv-05762, 2014 WL 202787, at *6-8 (S.D.W. Va. Jan. 17, 2014) (decision based on California law).

There may be extraordinary cases where medical records are ultimately deemed to establish a limitations defense conclusively. The surgeon, for instance, might write a note saying he told the patient he had recently discovered that the mesh he implanted in her is defective and her pain is likely caused by the defect in the mesh. But those cases will be the exception rather

than the norm. Moreover, even in those cases, Plaintiffs will have the right to conduct discovery of the physicians narrating the records to test the adverse inference from the records. The bottom line is that once Defendants go beyond the pleadings and into evidence to seek dismissal, Plaintiffs must be given the opportunity to conduct discovery to attempt to uncover contrary evidence.

Finally, the scheme by which Defendants claim they will seek dismissal is procedurally and substantively invalid. Procedurally, a motion for a "show cause" order is not a viable substitute for a motion for summary judgment. Substantively, such a maneuver would shift the burden of proof away from the party asserting the defense. This, the law does not countenance.

4. Defendants' bankruptcy defense does not justify the onerous discovery defendants propose.

The potential defense of a bar in bankruptcy does not somehow change a litigant's discovery obligations, any more than the limitations defense does. The contents of the Plaintiff Profile Form questionnaire were driven by Defendants' input. Indeed, Defendants proposed the questions relating to bankruptcy filings. If a Plaintiff has failed to answer the questions completely, Defendants can identify that Plaintiff on the list of deficient PPFs that the Court has ordered. But there is no authority for compelling a Plaintiff to sign an affidavit containing the legal conclusions Defendants suggest.

Moreover, some of the clients' bankruptcy filings are undoubtedly decades old, thus securing all the records defendants request would not just be difficult but impossible. Defendants cite no evidence suggesting that a substantial number of Plaintiffs who once filed for bankruptcy protection now lack standing or are subject to judicial estoppel. There is therefore no justification for imposing a new and substantial discovery burden on Plaintiffs.

CONCLUSION

For the reasons stated, Plaintiffs urge the Court to deny Defendants' Motion to Revise Case Management Procedures Related to Statute of Limitations and Estoppel Defenses.

Dated: February 4, 2015.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2015, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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